JUN 2 8 2001

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K002409

1. *Name of Submitter, Contact Person and Date Summary Prepared:*

Michael Mitsunaga
Automatic Medical Technologies, Inc.
21250 Hawthorne Blvd., Suite 560
Torrance, California 90503
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Summary Prepared On: April 30, 2001

2. *Device Name:*

Trade/Proprietary Name:	MaxOne™ IV Fluid/Blood Warmer
Common/Usual Name:	Blood, Blood Products and IV Fluid Warmer
Classification Name:	Infusion Fluid Thermal Warmer and Nonelectromagnetic Blood and Plasma Warming Device

3. *Legally Marketed Equivalent Device Name:*

We are claiming substantial equivalence to Augustine Medical's Bair Hugger Blood/Fluid Warmer, cleared 510(k) K973741, and Level 1 Technologies' Hotline Fluid Warmer, cleared 510(k) K911383.

4. *Description of the Device:*

The MaxOne™ IV Fluid/Blood Warmer consists of a single reusable heating unit with controller containing an on/off switch to be used with disposable MaxOne™ Warmer Cartridges. The device is placed in-line between a standard IV drip set and a standard IV extenstion set and is designed to warm blood, blood products and intravenous liquids at flow rates of up to and including 150 mL/min. The MaxOne™ IV Fluid/Blood Warmer will deliver temperatures at 33°C to 39°C.

The MaxOne™ IV Fluid/Blood Warmer opens up to reveal the aluminum heating plates. A disposable sterile MaxOne™ Warmer Cartridge is placed on the supporting pins of the aluminum heating plates. Blood, blood products and

intravenous solutions travel through channels in the warmer cartridge, which is surrounded by heating channels and heated by means of electrical resistance. The device meets the requirements of UL-2601 and IEC 60601-1.

5. *Intended Use of the Device*

The MaxOne™ IV Fluid/Blood Warmer is indicated for the warming of blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments.

6. *Comparison of technological characteristics With Predicate Device*

The MaxOne™ IV Fluid/Blood Warmer is substantially equivalent to Augustine Medical's Bair Hugger Blood/Fluid Warmer, cleared 510(k) K973741 and Level 1 Technologies' Hotline Fluid Warmer, cleared 510(k) K911383.

Comparison of Technological Features

Features	MaxOne™	Bair Hugger	Hotline
Heating method	Aluminum heating plates formed to accept warming cartridge, electrical resistance	Aluminum plates heated by electrical resistance	Circulating water heated by regulated resistance heater
Fluid contact product to be used with heating unit	Sterile polycarbonate disposable cartridge	Two types of sterile disposable sets	Sterile disposable fluid warming set
Temperature controls	3 thermistors	Thermocouples	Circulating water heating system
Alarm	Visual – LED indicators	Audio/visual	Audible
Alarm conditions	When temperature reaches 40°C	When over and under temperature, activates at 33°C, 43°C and 46°C	When temperature reaches 41.5°C
Electronics	Microprocessor control	PID controlled	Proportional controller
Operation	110 VAC	100 - 120 VAC	120 VAC
Flow	5 – 150 mL/min	KVO - 500 mL/min	5 - 50 mL/min
Infusion Temp	33°C - 39°C	34°C – 41°C	37°C – 40°C
Dimensions	3.25"W x 1.7"L x 9.7"H	7½"W x 10"L x 4½"H	7.0"W x 8.3"L x 9.5"H
Weight	2 lbs. 10 oz.	7 lbs. 7 oz	Dry: 8 lbs. Wet: 11 lbs.

7. *Discussion of Nonclinical Studies*

Results of studies conducted on the sterile disposable MaxOne™ Warmer Cartridge demonstrate the material to be biocompatible for its intended use. In addition, performance data demonstrate the temperature accuracy of the device at different flow rates.

8. *Conclusion*

The MaxOne™ IV Fluid/Blood Warmer has similar technological characteristics and the same intended use as devices currently on the market. Therefore, because of the similarities to predicate devices, Automatic Medical Technologies, Inc. believes this new device does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2001

Mr. Michael Mitsunaga
President
Automatic Medical Technologies, Incorporated
3422 West Pico Boulevard
Los Angeles, California 90019

Re: K002409
Trade/Device Name: MaxOne™ IV Fluid/Blood Warmer
Regulation Number: 864.9205
Regulatory Class: II
Product Code: LGZ and BSB
Dated: April 30, 2001
Received: May 2, 2001

Dear Mr. Mitsunsaga:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications For Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002409

Device Name: MaxOne™ IV Fluid/Blood Warmer

Indications For Use:

The MaxOne™ IV Fluid/Blood Warmer is indicated for the warming of blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (✓) OR Over-The-Counter Use ( )

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Rebecca Cucurita

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002409